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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	**PAPER NUMBER**
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,858	GREIFENSTEIN, PETER	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *14-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-13 in the reply filed on 17 July 2006 is acknowledged and of Applicant's amendment to Claim 1 and election of Specie B: -

kernels of Prunus armenica

endosperm (copra) of cocos nucifera

leafs of rubus (blackberry)

myzelles of mycetes

Specie C: please elect "auxiliary means" as additional component and "drops" as one form of administration, in claim 4.

Specie D: solid-liquid extraction (claim 5) and subsequent partial evaporation (exactly: discontinous mash extract bath with water at 37°C for 120 hours, subsequently distillation of the extract, 5-times)

Specie E: -please elect liquid extract (extracta fluidica) in claim 9.

- please elect drops in claim 10.

Specie F: please elect diseases of the psyche in claim 13 in the reply filed on 20 November 2006 is acknowledged. The traversal is on the ground(s) that the claims are clearly directed to a single general inventive concept under 37 C.F.R. § 1.141. Applicant further argues that the European Patent Office examined the application on unity of invention, and the European Patent Office did not raise any objections against the unity of invention according to claims I through 16 in the International Search Report

dated 23 January 2005 (the English translation on file with the application) and that regarding the novelty and inventive step, please note that novelty and inventive step of the invention according to pending claims 1 through 16 have been examined by the European Patent Office and that the Examiner at the European Patent Office stated in his Written Opinion of the Intemational Searching Authority (according to PCT Rule 43bis. 1) that novelty and inventive step are present in the present case according to claims 1 through 16 (an English translation of the Written Opinion is on file with the application). Applicant further argues that the "cosmetic composition" reference (U. S. Patent No. 6,348,200) concerns a totally different technical field, a totally different problem, and a totally different affect when compared with the present invention regarding a "medicinal product" and that the Examiner cites U. S. Patent No. 6,348,200 B1 and notes that the reference teaches a cosmetic composition. Applicant further argues that note that "musaze and rubus leaves" are not disclosed in this reference. Rubus leaves (leaves of blackberries) are not mentioned in the cited U. S. Patent No. 6,348,200, therefore, two additional and very important components (musaze and rubus leaves as presently claimed in Applicant's claim 1) are not disclosed in the '200 patent and that these two additional components lead to advantages that include the medicinal product is suitable for treatment of Acquired Immune Deficiency Syndrome (AIDS) and/or cancer, malignant tumors, carcinomas and sarcomas, and/or diseases of the psyche or the nervous system, which is substantially different than the cosmetic composition described in the cited U. S. Patent No. 6,348,200.

This is not found persuasive because Group I is drawn to a medicinal product characterized in that through a content of components and/or extracts of *Prunus armenica* and of *Cocos nucifera* and of *Humulus lupulus* and germinated barley or germinated rye or germinated wheat and of mycete and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, and from musaze and from rubus leaves, in each case as an active ingredient, whereas Group II is drawn to a method of using components and/or extracts of *Prunus armenica* and of *Cocos nucifera* and of *Humulus lupulus* and germinated barley or germinated rye or germinated wheat and of mycete and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, and from musaze and from rubus leaves, for preparation of a medical product for treatment of Acquired Immune Deficiency Syndrome (AIDS), whereas Group III is drawn to a method of using components and/or extracts of *Prunus armenica* and of *Cocos nucifera* and of *Humulus lupulus* and germinated barley or germinated rye or germinated wheat and of mycete and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, and from musaze and from rubus leaves, for preparation of a medical product for treatment of cancer, malignant tumors, carcinomas and sarcomas, whereas Group IV is drawn to a method of using components and/or extracts of *Prunus armenica* and of *Cocos nucifera* and of *Humulus lupulus* and germinated barley or germinated rye or germinated wheat and of mycete and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, and from musaze and from rubus leaves, for preparation of a medical product for treatment of diseases of the psyche or the nervous system. A search for the composition of Group I is not co-

extensive with a search for any of the methods because the composition of Group I may be used in a materially different process of using that product. Furthermore, Claim 1, at least is anticipated by or obvious over Nakajima (US Patent Number: 6348200 B1); Date of Publication: February 19, 2002. See Reference A). Nakajima teaches a cosmetic composition comprising of components and/or extracts of *Prunus armenica* and of *Cocos nucifera* and of *Humulus lupulus* and germinated barley or germinated rye or germinated wheat and of mycete and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, and from musaze and from rubus leaves, in each case as an active ingredient (See Column 12, continued into Column 13). Please note, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims. Consequently, the special technical feature which links the

claims does not provide a contribution over the prior art, so unity of the invention is lacking.

In response to Applicant's argument that the "cosmetic composition" reference (U. S. Patent No. 6,348,200) concerns a totally different technical field, a totally different problem, and a totally different affect when compared with the present invention regarding a "medicinal product" and that the Examiner cites U. S. Patent No. 6,348,200 B1 and notes that the reference teaches a cosmetic composition, that "musaze and rubus leaves" are not disclosed in this reference. Rubus leaves (leaves of blackberries) are not mentioned in the cited U. S. Patent No. 6,348,200, therefore, two additional and very important components (musaze and rubus leaves as presently claimed in Applicant's claim 1) are not disclosed in the '200 patent and that these two additional components lead to advantages that include the medicinal product is suitable for treatment of Acquired Immune Deficiency Syndrome (AIDS) and/or cancer, malignant tumors, carcinomas and sarcomas, and/or diseases of the psyche or the nervous system, which is substantially different than the cosmetic composition described in the cited U. S. Patent No. 6,348,200, **evidence must be submitted to show that the claimed invention has unexpected results**. See MPEP 716.02-716.02 (g), but more specifically see the following:

MPEP 716.02, which states:

Any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Waymouth*, 499 F.2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974); *In re Wagner*, 371 F.2d 877, 884, 152 USPQ 552, 560 (CCPA 1967); *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992).

MPEP 716.02 (c), which states,

"**Evidence of unexpected results must be weighed against evidence supporting *prima facie* obviousness in making a final determination of the obviousness of the claimed invention**. *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978)

Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). See also *In re Peterson*, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003); *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983); *In re Eli Lilly*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990)."

MPEP 716.02 (d), which states,

"Where the unexpected properties of a claimed invention are not shown to have a significance equal to or greater than the expected properties, the evidence of unexpected properties may not be sufficient to rebut the evidence of obviousness. *In re Nolan*, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977)

The nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof. *In re Kollman*, 595 F.2d 48, 201 USPQ 193 (CCPA 1979); *In re Lindner*, 457 F.2d 506, 509, 173 USPQ 356, 359 (CCPA 1972).

To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960)."

Please also note that the reference may be used as part of an obviousness argument. So, although it is noted that U. S. Patent No. 6,348,200 does not teach musaze or rubus leaves, this does not mean that this reference cannot be combined

with another to form an obviousness rejection.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Since there appears to be no contribution over the prior art, unity of the invention is, indeed, lacking.

In response to Applicant's argument that there was no lack of unity found by the European Patent Office in the corresponding PCT application, please note that the MPEP 1850 (I) states,

"Any international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (PCT Article 3(4)(iii)

and 17(3)(a), PCT Rule 3.1, and 37 CFR 1.475). Observance of this requirement is checked by the International Searching Authority and may be relevant in the national (or regional) phase.

The decision in *Caterpillar Tractor Co. v. Commissioner of Patents and Trademarks*, >650 F.Supp. 218,< 231 USPQ 590 (E.D. Va. 1986) held that the Patent and Trademark Office interpretation of 37 CFR 1.141(b)(2) as applied to unity of invention determinations in international applications was not in accordance with the Patent Cooperation Treaty and its implementing regulations. In the Caterpillar international application, the USPTO acting as an International Searching Authority, had held lack of unity of invention between a set of claims directed to a process for forming a sprocket and a set of claims drawn to an apparatus (die) for forging a sprocket. The court stated that it was an unreasonable interpretation to say that the expression "specifically designed" as found in former PCT Rule 13.2(ii) means that the process and apparatus have unity of invention if they can only be used with each other, as was set forth in MPEP § 806.05(e).

Therefore, when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. No change was made in restriction practice in United States national applications filed under 35 U.S.C. 111 outside the PCT."

Therefore, the Office determines whether there is lack of unity at the national stage regardless of whether the European Patent Office found a lack of unity.

Applicant further elected the following species: "lyophilized powder" from Claim 3, "tonicity" from Claim and nasal drops from Claim 11, with traverse. However, Applicant did not provide any grounds for traversal for the species election. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-16 are currently pending.

Claims 14-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 17 July 2006, 25 September 2006, and 20 November 2006.

Claims 1-13 are under examination.

Specification

The abstract of the disclosure is objected to because the term "musaze" is not defined nor understood, the term "prunus armenica" is misspelled throughout the entire specification, the Latin names, such as prunus armeniaca, cocos nucifera and humulus lupulus should be written as follows: *Prunus armeniaca*, *Cocos nucifera* and *Humulus lupulus*, and the entire language of the disclosure is generally narrative and indefinite, failing to conform with current U.S. practice. The disclosure appears to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Correction is required. See MPEP § 608.01(b).

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: "musaze", which is not defined in the specification or in the claims and it is unclear as to what Applicant is referring.

The disclosure is also objected to because of the following informalities: the term "prunus armenica" is misspelled throughout the entire specification, the Latin names, such as prunus armeniaca, cocos nucifera and humulus lupulus should be written as follows: *Prunus armeniaca*, *Cocos nucifera* and *Humulus lupulus*, and the entire language of the disclosure is generally narrative and indefinite, failing to conform with current U.S. practice. The disclosure appears to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: A medicinal composition comprising (specific ingredients written properly).

Claim Objections

Claims 1, 3 and 11 are objected to because of the following informalities: Latin names, such as prunus armeniaca, cocos nucifera and humulus lupulus should be written as follows: *Prunus armeniaca*, *Cocos nucifera* and *Humulus lupulus.* Furthermore, Applicant has misspelled "prunus armenica". The correct spelling is *Prunus armeniaca*. Appropriate correction is required.

Claims 4 and 10 are objected to because of the following informalities: the claim as written recites, "The medicinal product according to claim 1, characterized in that in addition to the extracts and/or component extracts in accordance with claim 1 it

comprises common carrier materials, auxiliary means and/or additives and is made up in the form of a tablet or a sugar coated tablet or a suppository or drops". Is Applicant claiming that the composition further comprises carriers, auxiliary material and/or additives and that the composition is in the form of a tablet, sugar coated tablet, suppository or drops? The objection applies to claim 10. The way the claims are written is confusing and both claims need to be rewritten to properly convey the invention. Appropriate correction is required.

Claim 12 is objected to because of the following informalities: claim 12 recites, "The medicinal product according to claim 1 characterized in that the active ingredients mycete is selected from the group, which comprises chlorophyll-free, eukaryontic organisms, especially protoctista (fungus like protista) and/or fungi (higher fungi)". Please note that "eukaryontic" is misspelled. The correct spelling is eukaryotic. Furthermore, this claim is poorly written and should be amended. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is "*whatever is now claimed*" (See page 1117).

A review of the language of the claim indicates that these claims are drawn to "A medicinal product comprising extracts of prunus armenica and of cocos nucifera and of humulus lupulus and of germinated barley and of mycete, and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, musaze and of rubus leaves, in each case as active ingredient".

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that,

while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B (1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention". Hence, an adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984). Accordingly, a medicinal product comprising musaze in the absence of knowledge as to what the material consists of or the source of the material is not a description of the material. In the instant case, on page 1 of the specification, Applicant discloses that "Within the framework of the present invention a medicinal product is provided, which comprises a content of ingredients and/or extracts of prunus armenica and of cocos nucifera and of humulus lupulus and germinated barley or germinated rye or germinatated wheat and of mycete and the liquid obtained by alcoholic fermentation of the grape juice of grapevines and from musaze and from rubus leaves, in each case as the active ingredient", on page 2 of the specification, Applicant discloses "So the medicinal product in accordance with the invention can for example have a content of pulp or kernels of prunus armenica and fibers or endosperm of cocos nucifera and

multiple fruit of humulus lupulus and germinated barely or germinated oats or germinated rye or germinated wheat and cell filaments or myzelles of mycetes and the liquid obtained by alcoholic fermentation of grape juice from the grapevine and the fruits or hulls of musaze and rubus" and on page 4 of the specification , Applicant further discloses, "In an especially preferred embodiment the medicinal product can have a content of ingredients and/or extracts of prunus armenica in the range for example of 10 wt % to 20 wt % and of cocus nucifera for example in the range from 10 wt % to 20 wt % and of humulus lupulus for example in the range from 10 wt % to 20 wt % and of germinated barley for example in the range from 10 to 20 wt % and of germinated rye in the range from 10 wt % to 20 wt % or germinated wheat from 10 wt % to 20 wt % and from mycete for example in the range from 10 wt % to 20 wt % and the liquid obtained by alcoholic fermentation of grape juice of the grapevine for example in the range from 10 wt % to 20 wt % and of musazes for example in the range from 10 wt % to 20 wt % and of rubus leaves for example in the range from 10 wt % to 20 wt %, in each case as the active ingredient and if necessary together with the usual carrier materials, auxiliary means and/or additive materials", on page 5 of the specification, Applicant discloses, " In accordance with the invention the components and/or extracts of prunus armenica and of cocos nucifera and of humulus lupulus and germinated barley or germinated rye, or germinated wheat and of mycete, and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, and from musaze and from rubus leaves, for preparation of a medicinal product are useful for treatment of Acquired Immune Deficiency Syndrome (AIDS)" and "Alternatively or additionally the components and/or

extracts of prunus armenica and of cocos nucifera and of humulus lupulus and germinated barley or germinated rye, or germinated wheat and of mycete and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, and from musaze, and from rubus leaves for preparation of a medicinal product are useful for treatment of cancer, malignant tumors, carcinomas and sarcomas", on page 6 of the specification, Applicant discloses, "Alternatively or additionally the components and/or extracts content of prunus armenica and of cocos nucifera and of humulus lupulus and germinated barley or germinated rye, or germinated wheat and of mycete and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, and from musaze, and from rubus leaves are useful for preparation of a medicinal product for treatment of diseases of the psyche or of the nervous system" and "It has been shown furthermore that the components and/or extracts content of prunus armenica and of cocos nucifera and of humulus lupulus and germinated barley or germinated rye, or germinated wheat and of mycete and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, and from musaze, and from rubus leaves for preparation of a medicinal product, are useful for treatment of diabetes diseases". However, other than the compositions described by Applicant, wherein Applicant simply states "A medicinal product comprising extracts of prunus armenica and of cocos nucifera and of humulus lupulus and of germinated barley and of mycete, and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, musaze and of rubus leaves, in each case as active ingredient" and the pages of the specification mentioned above, Applicant fails to adequately describe as to what Applicant defines or considers as

"musaze". For example, nowhere in the present specification does Applicant render a definition of the term "musaze" nor does Applicant cite an example of this term thereof.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of what constitutes "musaze". The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claims 1 and 11 are rendered uncertain by the phrase "A medicinal product comprising extracts of prunus armenica and of cocos nucifera and of humulus lupulus and of germinated barley and of mycete, and the liquid obtained from alcoholic fermentation of the grape juice of grapevines, musaze and of rubus leaves, in each case as active ingredient" (Claim 1) and "The medicinal product according to claim 1, characterized in that it can have a content of ingredients and/or extracts of prunus armenica in the range of 10 wt % to 20 wt % and of cocus nucifera in the range from 10 wt % to 20 wt % and of humulus lupulus in the range from 10 wt % to

20 wt % and of germinated barley in the range from 10 to 20 wt % and of germinated rye in the range from 10 wt % to 20 wt % or germinated wheat from 10 wt % to 20 wt % and from mycete in the range from 10 wt % to 20 wt % and the liquid obtained by alcoholic fermentation of grape juice of the grapevine for example in the range from 10 wt % to 20 wt % and of musazes for example in the range from 10 wt % to 20 wt % and of rubus leaves in the range from 10 wt % to 20 wt %, in each case as the active ingredient together with the usual carrier materials, auxiliary means and/or additives. " (Claim 11) because it is unclear as to what the composition in both claims comprise. Do the compositions comprise extracts of prunus armenica, cocos nucifera, humulus lupulus, germinated barley, mycete, musaze, rubus leaves and of the liquid obtained from alcoholic fermentation of the grape juice of grapevines or is Applicant claiming a composition comprising extracts of prunus armenica, cocos nucifera, humulus lupulus, germinated barley and mycete and further comprising liquid obtained from alcoholic fermentation of the grape juice of grapevines, musaze and rubus leaves, or is Applicant claiming a composition comprising extracts of prunus armenica, cocos nucifera, humulus lupulus, germinated barley and mycete and further comprising liquid obtained from alcoholic fermentation of the grape juice of grapevines, liquid obtained from alcoholic fermentation of musaze and liquid obtained from alcoholic fermentation of rubus leaves, or is Applicant claiming a composition comprising extracts of prunus armenica, cocos nucifera, humulus lupulus, germinated barley and mycete and further comprising an extract of (the) liquid obtained from alcoholic fermentation of the grape juice of grapevines, extract of (the) liquid obtained from alcoholic fermentation of

musaze and extract of (the) liquid obtained from alcoholic fermentation of rubus leaves or something else? Furthermore, the term "musaze" is not a recognized ingredient. What is "musaze"? Is "musaze" a plant, a fungus, a bacteria, an animal? Is "musaze" a term to describe a product or a type of extract or a by-product? Does "musaze" have a Latin name or a common name? What does Applicant mean by "liquid obtained from alcoholic fermentation of the grape juice of grapevines"? Is Applicant claiming wine? Finally, what does Applicant mean by "in each case as active ingredient"? Clearly all of the ingredients are required as part of the composition and contribute in some way to the composition as a whole. Applicant should omit this statement since it is clear that the composition requires all of these ingredients. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Please note that all of the claims contain many of the same issues as Claim 1 and should be corrected accordingly. Below the other issues with the claims are addressed but this in no way exempts the claims from the rejections made above with respect to claim 1 and the corrections made to claim 1 should be applied to all other claims where appropriate in conjunction with any additional corrections necessitated by the rejections below.

The metes and bounds of Claim 2 are rendered uncertain by the phrase "The medicinal product according to Claim 1, characterized in that it consists of the active ingredient components in accordance with Claim 1 and their pulp, multiple fruit, juice, milk, kernels, fibers, cell filaments, myzelles, endosperm, leaves, blossoms, buds, hulls

or stalks" because it is unclear as to what Applicant is claiming an extract from each of the ingredients listed in claim 1 wherein the part extracted is the pulp, multiple fruit, juice, milk, kernels, fibers, cell filaments, myzelles, endosperm, leaves, blossoms, buds, hulls or stalks of each ingredient or is Applicant? What does Applicant mean by "their" in the phrase "their pulp, multiple fruit, juice, milk, kernels, fibers, cell filaments, myzelles, endosperm, leaves, blossoms, buds, hulls or stalks"? Is Applicant referring to all ingredients, all extracts or each ingredient individually, wherein specific parts are used (either all or one or more)? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 3 are rendered uncertain by the phrase "The medicinal product according to Claim 1 characterized in that through a content of pulp or kernels of prunus armeinica and fibers or endosperm of cocos nucifera and multiple fruit of humulus lupulus and germinated barley or germinated oats or germinated rye or germinated wheat and cell filaments or myzelles of mycetes, and the liquid obtained by alcoholic fermentation of grape juice from the grapevine and the fruits or hulls of musaze and rubus leaves, in each case as an active ingredient". What does Applicant mean by "characterized in that through a content of pulp or kernels of prunus armeinica and fibers or endosperm of cocos nucifera and multiple fruit of humulus lupulus and germinated barley or germinated oats or germinated rye or germinated wheat and cell filaments or myzelles of mycetes, and the liquid obtained by alcoholic fermentation of grape juice from the grapevine and the fruits or hulls of musaze and rubus leaves, in

each case as an active ingredient? This entire claim is poorly written and confusing and needs to be rewritten. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claims 5-9 are rendered uncertain by the phrase "The medicinal product according to claim 1, characterized in that the extract can be obtained by solid-liquid or liquid-liquid extraction of the individual components or the active ingredient component mixture with the help of common extraction means, and by subsequent partial or complete evaporation of the extraction solution" (Claim 5), "The medicinal product according to claim 1, characterized in that it is a question of whether there is hot or cold extraction as well as whether the extraction method is continuous or discontinuous" (Claim 6), "The medicinal product according to claim 1, characterized in that the continuous extraction method is a Soxhlet extraction, perforation or a percolation, while the discontinuous extraction method can be a shaking out, leaching out or digestion" (Claim 7), "The medicinal product according to claim 1, characterized in that the extract represents one of one fixed active ingredient content adjusted extract from one individual active ingredient or from the entire mixture of active components, which can be obtainable by means of maceration or percolation using ethanol or an ethanol-water mixtures" (Claim 8) and "The medicinal product according to claim 1, characterized in that the medicinal product is a dry extract (extracta sicca) and/or a liquid extract (extracta fluidica) and/or a viscous extract (extracta spissa)" (Claim 9) because it is unclear as to what Applicant is claiming. It appears that Applicant is

attempting to describe methods of extraction but the language is ambiguous and confusing and all of the above claims need to be corrected to adequately describe the methods and solvent systems Applicant is attempting to claim. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 13 are rendered uncertain by the phrase "The medicinal product according to claim 1 characterized in that it is suitable for treatment of Acquired Immune Deficiency Syndrome (AIDS) and/or cancer, malignant tumors, carcinomas, sarcomas and/or diseases of the psyche or of the nervous system". What is a disease of the psyche and a disease of the nervous system? The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

All of the claims (1-13) are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Please rewrite all of the claims to better describe the intended invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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February 20, 2007

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